FIOR & GENTZ

Instructions for Use for Patients
System Knee Joint NEURO HiTRONIC

EN

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Instructions for Use for Patients
System Knee Joint **NEURO HiTRONIC**

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ electrohydraulic system knee joint from a qualified specialist in orthopaedic technology.

1. Safety Instructions

1.1 Classification of the Safety Instructions

⚠ **DANGER**	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
⚠ **WARNING**	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
⚠ **CAUTION**	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
NOTICE	Important information about a possible situation which, if not avoided, leads to damage of the product.

All serious incidents according to Regulation (EU) 2017/745 which are related to the product have to be reported to the manufacturer and to the competent authority of the Member State in which the qualified specialist in orthopaedic technology and/or the patient is established.

1.2 All Instructions for Your Safety

⚠ DANGER

Potential Traffic Accident Due to Limited Driving Ability
Gather information about all issues concerning safety and security and potential dangers before driving a motor vehicle with orthosis.

⚠ DANGER

Risk of Strangulation Due to Improper Handling of the Cables
Use the orthosis as described in these instructions for use. During use, pay particular attention to the connection cable of the orthosis as well as to the charging cable of the controller.

⚠ WARNING

Jeopardising the Therapy Goal by Not Providing the Necessary Free Movement
Check if the system joint moves freely in order to avoid restrictions of the joint function.

⚠ WARNING

Risk of Falling Due to Permanent Higher Load
Do not engage in sport activities with the orthosis that expose it to excessive load. If your patient data has changed (e.g. due to weight gain, growth or increased activity), consult a qualified specialist in orthopaedic technology and have them check the suitability of your orthosis with regard to the changed load. You will find the next maintenance appointment in your orthosis service passport.

⚠ WARNING

Risk of Falling Due to Improper Shoe/Wrong Shoe Pitch
Wear a shoe to which your orthosis is adjusted to avoid joint dysfunction in Auto mode.

⚠ WARNING

Risk of Falling Due to Improper Handling
Have a qualified specialist in orthopaedic technology inform you about the correct use of the system joint and potential dangers. Disable the permanent unlock function if you no longer wish to use it. Do not use the orthosis if you notice any damage on the system joint.

⚠ WARNING

Risk of Falling Due to Improper Handling
System joint components and orthosis components may only be demounted and maintained by a qualified specialist in orthopaedic technology. Any handling of the system joint and the orthosis from your side that goes beyond the activities described in these instructions for use is not permitted. Do not make any modifications to the system joint other than those specified as permissible in these instructions for use. In particular, do not loosen any screws on the system joint.

⚠ WARNING

Risk of Falling Due to Improper Dirt Removal
In order to avoid a failure of the lock function, remove dirt from the orthosis and the system joint as described in these instructions for use. Do not grease the system joint on your own. If necessary, consult a qualified specialist in orthopaedic technology.

⚠ WARNING

Risk of Falling Due to Damages to the Orthosis
Avoid damage to your orthosis and to the integrated electronics (e. g. due to shocks, knocks and fall). However, if your orthosis is damaged, switch it into Lock mode and contact a qualified specialist in orthopaedic technology as soon as possible.

⚠ WARNING

Risk of Falling Due to Incorrect Walking with the Orthosis
Consult a qualified specialist in orthopaedic technology about the correct use of your orthosis and the particularities of the system joint. If necessary, we recommend a physiotherapeutic gait re-education.

⚠ WARNING

Risk of Falling Due to Unintentional Performing of the Gesture
The use of gestures reduces the safety when using the orthosis. Only have a qualified specialist in orthopaedic technology activate the gesture for sitting down in Auto mode if you are physically fit so that you do not fall if the gesture is performed unintentionally.

⚠ WARNING

Risk of Falling Due to Changes in the Orthosis
If you notice any changes in the orthosis (e.g. loosely attached joint components, loosened screws, play in the system joint or change in performance), immediately contact a qualified specialist in orthopaedic technology. Do not secure screws for the system joint on your own. All settings must be checked by a qualified specialist in orthopaedic technology before handing over the orthosis and during the maintenance appointments. You will find the next maintenance appointment in your orthosis service passport.

⚠ WARNING

Risk of Falling Due to Use of Unauthorised Accessories
Use only the accessories specified or supplied by the manufacturer (power supply unit, charging cable) in order to avoid increased electromagnetic emissions and reduced electromagnetic immunity of the knee joint system.

⚠ WARNING

Risk of Falling Due to Electromagnetic Interference
Do not use the knee joint system in close proximity to or stacked with other portable RF communication devices in order to avoid impairing the function of the knee joint system. If such use is necessary, observe the knee joint system and other portable RF communication devices in use to ensure that they function normally.

⚠ WARNING

Risk of Falling Due to Electromagnetic Interference
Use portable RF communication devices (including peripherals such as antenna cables and external antennas) at a safety distance of at least 30cm from all components of the knee joint system to avoid impairing the function of the knee joint system. If use at a distance of less than 30cm is necessary, observe the knee joint system during use to ensure that it functions normally. Also note the safety distances for RF communication devices specified in these instructions for use (see paragraph 19.6).

⚠ WARNING

Risk of Falling Due to Security Gaps in the Software
Carry out regular updates for your mobile device. Make sure that your **User** app and the operating system of your mobile device are always working with the latest version.

⚠ WARNING

Risk of Electric Shock Due to Improper Handling
Only use the supplied accessories to avoid electric shock and damage to the knee joint system.

⚠ WARNING

Risk of Injury Due to Improper Handling of the Controller or Remote Control
Use the controller and the remote control as described in these instructions for use. The orthosis may not be worn while it is charging. The controller is a sensitive electronic device with an integrated lithium-polymer battery. When handling the controller please avoid:
- strong heat (e.g. fire, heater, fireplace);
- charging of a battery in direct sunlight;
- knocks and shocks (e.g. by pets) as well as
- immersion in water.

⚠ WARNING

Risk of Injury Due to Improper Handling of the System Joint
Use the system joint as described in these instructions for use.
- Do not immerse the system joint in water. The electronic system components (excluding the accessories) are only protected from water splashing on all sides.
- When using the system joint, an opening is formed between the joint's upper and lower parts, in which clothing or skin could get caught.

NOTICE

Limitation of the Joint Function Due to Electrostatic/Magnetic Field
Please note that, while using the orthosis, an electrostatic and magnetic field (e.g. MRI) can lead to joint dysfunction.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance
Have a qualified specialist in orthopaedic technology inform you about the maintenance intervals to be observed in order to avoid joint dysfunctions. You will find the next maintenance appointment in your orthosis service passport.

NOTICE

Damage to the Controller Due to Improper Handling
Use the controller as described in these instructions for use. In particular, please ensure that the controller:
- is used with the provided charging cable and power supply unit, and
- is only used at ambient temperatures from -10°C to +40°C.

NOTICE

Damages to the Controller and Remote Control Due to Improper Handling
Ensure the correct use in order to avoid joint dysfunction. Regarding the controller and remote control, avoid:
- opening them as well as
- using them in areas where radio waves are forbidden (e.g. in planes, hospitals).
Ask the responsible staff on-site how to use them.

In case of problems with the system joint and potentially occurring allergic reactions, contact a qualified specialist in orthopaedic technology or the manufacturer. You can find the manufacturer's contact data on the back page of these instructions for use.

2. Use

2.1 Intended Use

The FIOR & GENTZ electrohydraulic system knee joints must be used exclusively for the orthotic treatment of the lower extremity. The system joint provides stance phase control and is only allowed to be used for producing a KAFO. Every system joint influences the orthosis' function and thus also the function of the leg.

2.2 Indication

The indications for the treatment with an orthosis for the lower extremity are insecurities when standing and walking that lead to a pathological gait. This can be caused, for example, by paralyses, structurally conditioned deformities/malfunctions or as a result of neurological disorders (such as stroke or PAD), physical trauma and/or surgery.

The physical conditions of the patient, such as muscle strength or activity level, are crucial for the orthotic treatment. A safe handling of the orthosis must be ensured. A qualified specialist in orthopaedic technology selects the appropriate system joints for the orthosis.

2.3 Contraindication

The system joint is not suitable for treatments that were not described in paragraph 2.2, such as a treatment of the upper extremity or a treatment with a prosthesis or ortho-prosthesis, for example after amputations of leg segments.

2.4 Qualification

The system joint must only be handled by a qualified specialist in orthopaedic technology.

2.5 Application

All FIOR & GENTZ system joints were developed for everyday life activities such as standing and walking. Extreme impact stress, which occurs for example during long jump, climbing, parachuting and football, is excluded. The system joint can be used at temperatures of -10°C to +40°C.

3. Knee Joint System

The knee joint system is equipped with **Bluetooth®** technology* and consists of the following components (fig. 1):

1. **system knee joint**
2. **controller**
3. **remote control** for the patient including **charging cable with power supply unit** and **User** app
4. **Expert** app for qualified specialists in orthopaedic technology

The system knee joint and the controller are built into your orthosis. The qualified specialist in orthopaedic technology uses the **Expert** app to adjust the orthosis. You need the remote control to operate the orthosis. In addition, you can also use the **User** app.

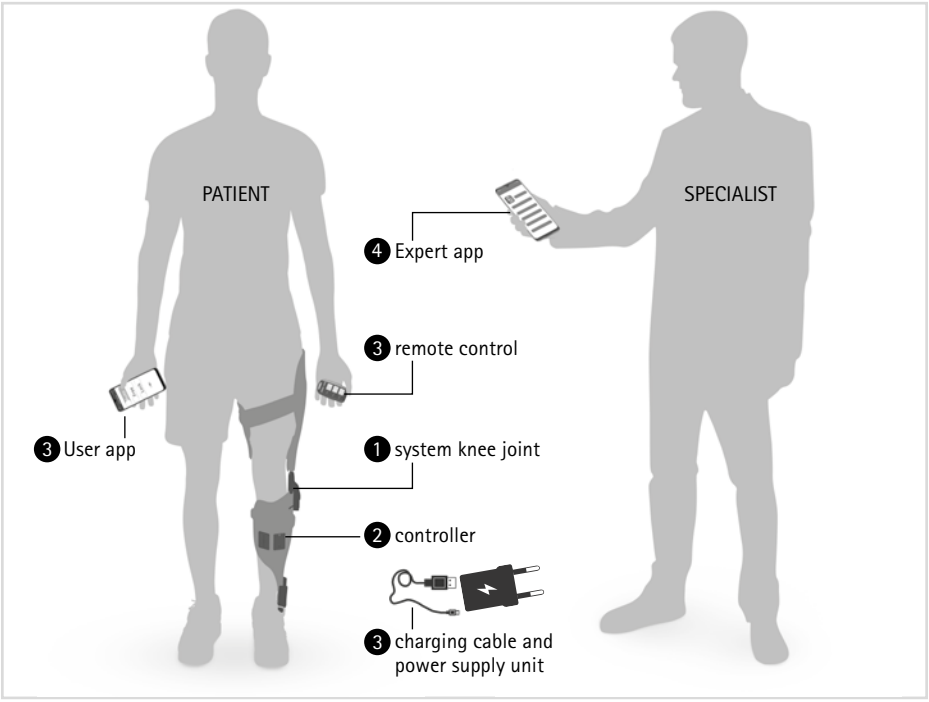


fig. 1

* The Bluetooth word mark and logos are registered trademarks of Bluetooth SIG, Inc. and any use of such marks by FIOR & GENTZ is under license.

The qualified specialist in orthopaedic technology has provided you with the following system components in addition to your orthosis (fig. 2):

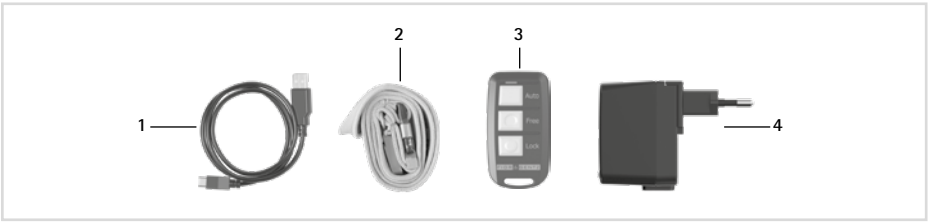


fig. 2

Item	Art. No.	Description	Unit	Quantity
1	ET0710-01	charging cable for controller, 1m	pce.	1
2	PR4000	lanyard FIOR & GENTZ	pce.	1
3	ET3840-P	remote control with Bluetooth	pce.	1
4	ET0780-01	power supply unit	pce.	1

3.1 Joint Functions

The **NEURO HiTRONIC** is a microprocessor-controlled, automatic system knee joint and provides four joint functions:

- basic function in delivery status in Auto mode
- alternative function in Lock mode
- alternative function in Free mode
- alternative function in permanent unlocking

The essential performance features of the automatic electronic system joint are to remain unlocked in Free mode and locked in Lock mode, as well as to lock or unlock at the right moment in Auto mode.

If electromagnetic interference occurs, the automatic knee joint system does not function as described in these instructions for use. Read the safety instructions before using the knee joint system to avoid problems.

3.1.1 Safe Handling of the Joint Functions

Standing Up From a Seated Position
Before standing up, the system knee joint must be set to Free mode. Once you are standing securely, you can switch to Auto or Lock mode.

Stance Phase Control

The system joint ensures the continuously variable stance phase in a knee angle of 0° (5°) to 45°. Stance phase control occurs between 45° and 50° contingent upon the load. If the load limit is exceeded, an overload protection takes effect. It is comparable to an electric fuse. If the overload protection is triggered, this may result in deformation of the roll holder and possibly its fracture. In this case, the roll unit must be replaced by a qualified specialist in orthopaedic technology.

3.1.2 Basic Function in Auto Mode

The controller of the orthosis has motion sensors that detect the movement and position of your lower leg. The controller locks and unlocks the system joint depending on which gait phase you are in.

Stance

When you are standing with your orthosis (fig. 3) or when you interrupt the step in stance phase, the system knee joint locks, as no movement is registered.

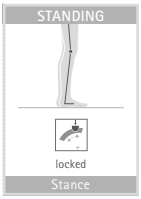


fig. 3

Gait

When walking, the system joint locks/unlocks as follows: the system joint is locked in the direction of flexion from mid swing to mid stance. In the gait phases from terminal stance to initial swing, the system joint is unlocked and is therefore free moving (fig. 4).

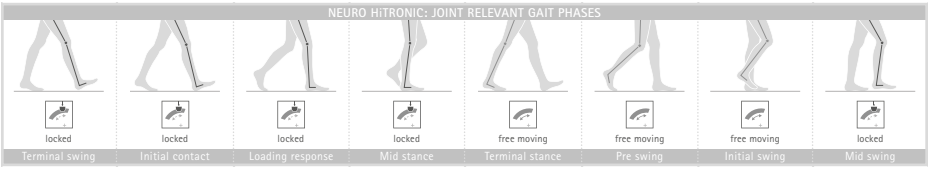


fig. 4

In the free moving phases terminal stance and pre swing, the system knee joint is not secured electronically in order to prepare the knee flexion for pre swing:

- In terminal stance, securing against knee flexion takes place via the levering back extension moment of the forefoot lever.
- If, contrary to expectations, weight is put on the leg with orthosis in pre swing when the step is interrupted in this phase, the system knee joint will not lock. Have a qualified specialist in orthopaedic technology explain this situation to you and, if necessary, train with them.

If the free moving phase initial swing is unexpectedly interrupted, the system knee joint will lock safely.

3.1.3 Alternative Function in Lock Mode

In Lock mode, the system knee joint is locked, i.e. bending the leg is prevented. Stretching remains possible.

3.1.4 Alternative Function in Free Mode

In Free mode, the system knee joint is unlocked, i.e. it is free moving up to a determined position.

3.1.5 Alternative Function in Permanent Unlocking

fig. 5

The system knee joint can be permanently unlocked mechanically, for example for activities such as driving a car or bicycle. In this mode it is guaranteed that the system knee joint does not lock unintentionally.

To do so, take a seat and unlock the system joint manually with the rotary switch below the system joint, by pressing in the rotary switch and then turning it in the direction of the symbol.

If you then press the Lock button on the remote control/app, you also save energy. The system knee joint remains unlocked even if you select another mode (e.g. Auto) with the remote control/app. In order to change the system joint's mode again with the remote control/app, turn the rotary switch in the direction of the symbol (fig. 5).

3.2 Rotary Switch

There is a rotary switch below the system joint (fig. 5). The three symbols show what happens if the rotary switch is turned in their respective direction. The arrows below show how the rotary switch should be controlled in order to select a symbol.

Symbol	Action	Meaning
	Turn the rotary switch in the direction of the symbol.	The system joint is operated from the remote control/app.
	Turn the rotary switch in the centre and press in.	The system joint is unlocked as long as the rotary switch is pressed in. As soon as it is released, the system joint will be operated once again from the remote control/app.
	Press in the rotary switch and turn it in the direction of the symbol.	The system joint is now in permanent, mechanical unlocking (see paragraph 3.1.5).

3.3 Remote Control

You can select the mode on your orthosis with the remote control. Make sure that you are standing securely when changing the mode of your orthosis. Every time you press a button on the remote control, the LED flashes briefly.

Remote Control	Item	Description	Meaning
	1	LED	The LED indicates light signals for the selected mode and the battery health.
	2	Auto button	The system joint switches into Auto mode.
	3	Free button	The system joint switches into Free mode.
	4	Lock button	The system joint switches into Lock mode.

Handle the remote control properly. If your remote control does not work as usual, do not try to open it. Contact a qualified specialist in orthopaedic technology.

3.4 **User** App

fig. 6

The app is intended to complement your remote control. It offers the same range of functions.

You can operate the orthosis either with the remote control and/or with the free app (fig. 6) via your smartphone/tablet or your Apple Watch* or Android Watch (fig. 7). Minimum requirements are Bluetooth 4.0 and Android 6.0 or iOS 12 for smartphones and Wear OS 3.0 or watchOS 4.2 for smartwatches.

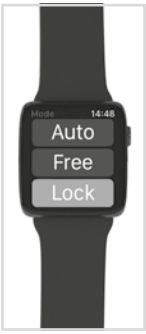


fig. 7

The orthosis can only be operated with the remote control or app to which it is currently connected. Other remote controls/apps have no influence on your orthosis.

Carry out regular updates for your mobile device and enable automatic updates. Make sure that your **User** app and the operating system of your mobile device are always working with the latest version. If the manufacturer of your mobile device no longer offers updates to fix bugs or security gaps, it is advisable to switch to a newer device.

* Apple Watch is a trademark of Apple Inc., registered in the U.S. and other countries.

3.4.1 Pairing

In this menu item of the **User** app, you can establish a connection between the controller of your orthosis and the **User** app. To do so, follow the instructions in the app.

3.4.2 Step Counter

The app gives you access to the step counter, which counts all steps you take with the leg with orthosis in the different modes. If you would like to know how many steps you have taken in total (with both legs), double the value.

3.4.3 Sound

In the sound settings, you can adjust the volume of the signal tones or switch them off.

3.4.4 Gestures

With this menu item, you can see if the gesture for sitting down in Auto mode has been activated. The first activation has to be carried out by a qualified specialist in orthopaedic technology. Afterwards, you can switch the function off and on yourself. This gesture unlocks the system joint for a short time while in Auto mode so that you can sit down. To do so, stand still in basic position for one second and then set down the affected leg with the heel and wait for another second. The system joint unlocks and you can sit down. The system joint locks as soon as the lower leg is put in a vertical position.

3.4.4.1 Gestures via Smartwatch

If you have an Apple Watch or a Samsung* Watch, you can alternatively activate sitting down in Auto mode with the gestures via smartwatch. You can find further information under **Gestures via Smartwatch** on the FIOR & GENTZ website (see QR code, fig. 8).

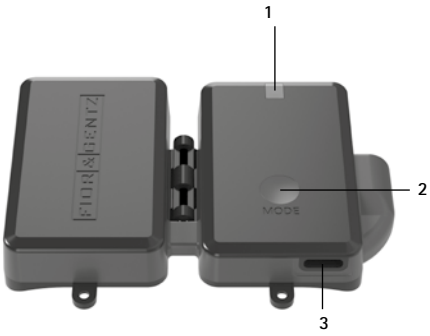
fig. 8

* Samsung is a registered trademark of Samsung Electronics Co., Ltd.

Minimum requirements for using the gestures via smartwatch are Apple Watch Series 4, Apple Watch SE (1st generation) or Apple Watch Ultra (1st generation) as well as Samsung Galaxy Watch 4.

3.5 Controller

The controller is mounted to your orthosis. It receives commands from the remote control/app, registers your movements and controls the system knee joint.

Controller with Integrated Lithium-Polymer Battery	Item	Description
	1	multicolour LED for battery charging, mode and Bluetooth connection
	2	MODE button
	3	charging port

3.6 Manual Mode Change

A MODE button, through which the orthosis can be operated manually, is built into the controller.

Depending on the mode that is already selected, it can be switched in the following order by pressing briefly: Auto, Free and Lock. This button is particularly important if you are travelling by plane, as it is possible that you may not be allowed to use the remote control/app during take-off, final approach or landing. You can generally use the remote control/app during the flight and after landing. For further information, please contact the flight crew.

The MODE button can only be used as long as the battery is not fully discharged. When the battery is fully discharged, you can only use the Lock mode.

If an automatic system knee joint has been combined with the **NEURO HiSWING R+** system ankle joint and both are connected to the same controller, the mode for the system knee joint can be changed by briefly pressing the MODE button. If the MODE button is pressed down for longer, the controller switches between Zero and standby for the **NEURO HiSWING R+**.

4. Connection between Controller and Remote Control/App

A qualified specialist in orthopaedic technology establishes the connection between the controller and the remote control. If you wish to operate the controller with the **User** app, use the app menu and select the desired menu item to establish a connection. Follow the additional instructions in the app.

4.1 Controlling Two Orthoses

If you are wearing two orthoses with a **NEURO HiTRONIC** knee joint system, you have the option of connecting the controllers of both orthoses with one or two remote controls. If you activate two remote controls, you can change the modes separately for each controller/orthosis. If you activate only one remote control, the modes of both controllers/orthoses are changed simultaneously. You can change the modes for both controllers or orthoses separately or at the same time with the **User** app.

5. Checking the Connection between Controller and Remote Control

Due to signals of the controller and the remote control, you will be informed if your remote control is connected with the controller. The LED at the remote control indicates that the remote control and the controller communicate with each other. There are different signals for a connection with one or two controllers.

If you have previously operated the orthosis with the app, you have to close the app in order to operate the orthosis with the remote control.

5.1 Indication of the Connection with One Controller

Remote Control	Light Signal	Meaning
 One of the three buttons was pressed.	**colour:** yellow, green, red (depending on battery status) **signal duration:** ■ 	The remote control is connected with the controller. The command was sent successfully.
	colour: red **signal duration:** ■ ■ ■ 	- The orthosis is in Sleep mode (see paragraph 8.2). - The battery is empty. - The remote control is too far from the orthosis.
	colour: blue (controller) **signal duration:** ■ 	The controller communicates with the remote control.

5.2 Indication of the Connection with Two Controllers

<table>
<tr><th>Remote Control</th><th>Light Signal</th><th>Meaning</th></tr>
<tr><td rowspan="8">
One of the three buttons was pressed.</td><td>colour: yellow, green, red (depending on battery status)</td><td rowspan="3">The remote control is connected with the controllers. The command was sent successfully to an orthosis.</td></tr>
<tr><td>signal duration: ■</td></tr>
<tr><td> </td></tr>
<tr><td>colour: red</td><td rowspan="3">- The orthoses are in Sleep mode (see paragraph 8.2).
- The batteries are empty.
- The remote control is too far from the orthoses.</td></tr>
<tr><td>signal duration: ■ ■ ■</td></tr>
<tr><td> </td></tr>
<tr><td>colour: yellow, green, red (depending on battery status) and afterwards red</td><td rowspan="3">The command was sent successfully to an orthosis.
- The second orthosis is in Sleep mode (see paragraph 8.2).
- The battery for the second orthosis is empty.
- The remote control is too far from the second orthosis.</td></tr>
<tr><td>signal duration: ■ . . . ■ ■ ■</td></tr>
<tr><td> </td></tr>
<tr><td>colour: blue (controller)</td><td rowspan="3">The controllers communicate with the remote control.</td></tr>
<tr><td>signal duration: ■</td></tr>
<tr><td> </td></tr>
</table>

6. Checking the Connection between Controller and User App

In order to operate the orthosis via the app, Bluetooth must be permanently switched on and the app must be open in the foreground. Use the menu of the app and select the desired menu item to connect to one or two controllers. Follow the additional instructions in the app.

An orthosis can only be operated with one app at the same time because there is a connection between the controller and the app. Other apps have no influence on the connected orthosis. You can continue to use the remote control instead of the app when the controller is connected to the remote control and is not actively communicating with the app. If there is an active connection to the app, the blue LED on the controller blinks permanently and the controller cannot be operated with the remote control. The app is intended to complement your remote control.

7. Checking the Mode and Battery Status

7.1 Indication of Mode and Battery Status on the Controller

You can see the mode and battery status of the controller on the remote control or in the app. Furthermore, the LED battery level indicator displays the following light signals for the battery status:

Light Signal	Meaning
colour: yellow, green, red (depending on battery status)	The controller is in Auto mode.
signal duration: ■	
colour: yellow, green, red (depending on battery status)	The controller is in Free mode.
signal duration: ■ ■	
–	The controller is in Lock mode.

The battery status is not displayed in Lock mode. It can be viewed on the remote control or in the app.

In combination with an automatic ankle joint system, the light signal only indicates the battery status and not the mode if at least one of the system joints is active.

The controller emits the following sound signals for the battery status when the battery is almost empty:

Sound Signal	Signal Duration							Cause	Meaning
	■ ■	break	■ ■	break	■ ■	break	■ ■		The battery is almost empty. Depending on the battery health, it takes a few hours to fully discharge the battery.
	0.5 sec.	1 sec.	0.5 sec.	1 min.	0.5 sec.	1 sec.	0.5 sec.		

Due to the importance of a properly functioning orthosis, this signal sounds every minute. This period can be extended to ten minutes by pressing one of the three mode buttons on the remote control/app. To do this, select the mode in which your orthosis is currently operating so that you do not inadvertently change modes. After ten minutes, the pause can always be extended by another ten minutes by pressing the mode button again. If no mode button is pressed, the signal will sound every minute. The sound signals for the battery status can be turned off until the next charge through the **User** app settings.

7.2 Indication of Battery Status on the Remote Control/in the App

If you operate the orthosis via the app, you can see the battery status of the controller(s) at any time in the app.

You can also check the status of the battery status of the controller(s) with your remote control. There are different signals for a connection with one or two controllers.

7.2.1 Indication of the Battery Status for a Connection with One Controller

Light signals for the remote control (with Auto mode example):

Remote Control	Light Signal				
	LED	Colour	Signal Duration	Meaning	
One of the three buttons was pressed.		green	■		The battery for the controller is fully charged.
		yellow	■		The battery status is low. Depending on the battery health, it takes max. 7 hours to fully discharge.
		red	■		The battery is almost empty. Depending on the battery health, it takes a few hours to fully discharge the battery.

7.2.2 Indication of the Battery Status for a Connection with Two Controllers

If your remote control is connected with two controllers, the light signal on the remote control does not apply automatically to both controllers but to that with the lowest battery. The battery status indicator on the controller or in the app (see paragraph 7.1) allows you to determine whether the batteries of both controllers are affected, or which orthosis requires its battery to be charged.

Example: the LED of the remote control flashes red after you have pressed one of the three buttons. The LED battery status indicator of the controller for the right orthosis blinks green, which means that the battery is full. The LED battery status indicator of the controller for the left orthosis blinks red. This orthosis should soon be charged.

8. Energy Consumption

8.1 Period of Use of Batteries in Different Modes

The following average battery life was determined at room temperature:

Auto	Free	Lock
26 000 strides	24 hours	over 2 weeks

8.2 Energy-Saving Modes

Your orthosis has three different energy-saving modes:

- If the orthosis is not moved in Auto or Free mode for more than **two hours**, the orthosis switches automatically into Lock mode. The Lock mode saves energy. If you press any button on the remote control, the orthosis will change back from Lock mode into the desired mode.
- If the orthosis is not moved for more than **30 minutes** in Lock mode, it will automatically switch into Sleep mode. In Sleep mode, the orthosis consumes very little energy. The controller no longer receives signals from the remote control/app. To switch back into Lock mode, move the orthosis slightly. The LED on the controller then lights up briefly in all colours.
- If the orthosis is not moved for more than **three days**, it switches automatically into Deep Sleep mode. In Deep Sleep mode the controller does not consume energy and no longer receives signals from the remote control/app. In order to put the orthosis back in operation, press the MODE button on the controller or connect the charging cable.

9. Handling of the Controller Battery

The controller has a long service life and battery lifespan. Do not try to disassemble the controller as the battery is a fixed part of the controller.

9.1 Charging the Lithium-Polymer Battery

You can charge the battery using the charging cable and power supply unit included in the scope of delivery, via a common household power socket. Always charge the battery fully and respect the general conditions of use and storage.

If the period of use of the orthosis considerably shortens despite fully charged batteries, contact a qualified specialist in orthopaedic technology.

10. Advice on Using Your Orthosis

10.1 Before Use

Pay attention to the following every time you use the orthosis:

- Check the battery status of the controller.
- Set the orthosis in Free mode in order to put it on.
- Set the rotary switch to the symbol so that you can operate the system joint via the remote control/app.

10.2 Bluetooth® Connection

The connection quality depends on how interference-free your environment is.

10.3 The Proper Shoe

A qualified specialist in orthopaedic technology adjusts your orthosis when you try it on and make your first steps. Since you have to get used to your new orthosis, the settings should be regularly checked in the first weeks and, if necessary, newly adapted to your need for safety. The orthosis is adjusted to the pair of shoes (shoe pitch) with which you start walking with your orthosis. If you want to wear other shoes, a qualified specialist in orthopaedic technology must ensure that the orthosis is also adjusted to these shoes.

10.4 Gait Re-Education

In order to be able to use your orthosis optimally, you should make use of a physiotherapeutic gait re-education.

In gait re-education, the following should be specially trained:

- walking upright, with the upper body slightly bent forward;
- applying as little body weight as possible on additional walking assistive devices (such as canes, parallel bars or walkers) as otherwise the physiological gait can be affected.

With gait re-education, you become more secure in using your orthosis, your gait pattern improves and you get used to your orthosis sooner. This is particularly important after many years of wearing a locked orthosis. Gait re-education can also be supported by acoustic signals from the orthosis. Ask a qualified specialist in orthopaedic technology for additional information. Be extremely careful when managing stairs, going on uneven surfaces or uphill/downhill. If you do not feel secure in using your orthosis in Auto mode yet, we recommend selecting Lock mode (see paragraph 3.1.3). Regularly report to a qualified specialist in orthopaedic technology your experiences with the orthosis during the first weeks. This is the only way you can get specific advice or help.

The more physiological the gait becomes, the better the orthosis can support you.

10.4.1 Walking with the Orthosis in Auto Mode

A qualified specialist in orthopaedic technology can change the setting for the first step to make walking easier for you. The following options are available:

- In the default setting, the detection of the first step is deactivated. This is the safest setting as the orthosis only unlocks in the second swing phase. For patients who feel very secure walking with their orthosis, the detection of the first step can be activated. In this case, start walking with the leg without orthosis. During the second step, the controller will then detect the first swing phase of the treated leg and the system knee joint is automatically unlocked. This enables a physiological gait.
- For patients who have both legs treated with orthoses, we recommend activating the detection of the first step for one of the orthoses. Decide which leg you want to start walking with. A qualified specialist in orthopaedic technology will then activate the detection of the first step for the orthosis on the other leg. You thus start walking with the orthosis in a locked state, which provides more stability.
- If you feel insecure with an unilateral treatment and make slow steps, the detection of the first step should not be activated.

10.5 Malfunction Due to External Impact

The system knee joint is provided with electronic components that react sensitively to very strong shocks. This can cause the system joint not to remain unlocked during the swing phase but to lock. The orthosis should then work in the previously set mode again. If this is not the case, change the mode with your remote control/app.

In general, try to avoid great damages to your orthosis, e.g due to shocks, knocks or falls because this may lead to failure of different system components and, in the worst case, of the orthosis. If you notice any damage on the orthosis, only use it in Lock mode and consult a qualified specialist in orthopaedic technology.

If there is a failure of the joint function, the orthosis switches automatically into Lock mode. Thus, it enables stability during stance and reduces the risk of falling.

If you would like to completely turn off the orthosis for safety reasons, press and hold the MODE button for approx. 17 seconds. This will cause a short beep to sound. After 6–10 seconds a longer beep will sound, and after an additional 10 seconds an extra long beep will sound. The orthosis will then switch into Deep Sleep mode (complete power interruption). If you would like to use the orthosis again, turn it back on by pressing the MODE button or by plugging in the charging cable.

10.6 Restrictive Use

The system knee joint has been tested for electromagnetic compatibility in accordance with the IEC 60601-1 standard for medical electrical devices. That means the orthosis works in an electromagnetic environment without introducing electromagnetic disturbances to other devices in that environment. Nevertheless, similar to smartphones, pay attention to whether or under what conditions you are allowed to use your orthosis in specially designated areas, because the integrated electronics use radio waves (Bluetooth) and can be affected by these as well. In specially designated areas (fig. 9), ask the responsible staff on site if you can use the orthosis without restrictions. If you are not allowed to use the remote control/app, change the mode using the MODE button (see paragraph 3.6) or, if needed, take off the orthosis.

fig. 9

11. Maintenance

Ask a qualified specialist in orthopaedic technology to maintain the system joint of your orthosis **regularly**. When the orthosis is handed over to you, you receive an orthosis service passport. Bring this orthosis service passport to each follow-up and let a qualified specialist in orthopaedic technology enter the next maintenance appointment. For your own safety, respect the maintenance appointments. Never carry out maintenance work or other adjustments and repairs yourself. In the case of children and people with cognitive impairments, we would like to point out to you as parents or care team that you must regularly check the orthosis and the system joint for signs of wear. If you notice any changes, immediately contact a qualified specialist in orthopaedic technology.

11.1 Dirt Removal

Remove dirt from the system joint on a regular basis. Use a dry cloth and clean the system joint only superficially. Then, remove visible dust and lint from the mechanics by using tweezers. Check the orthosis in straight and flexed position.

12. Storage

We recommend not storing the system joint in a damp environment.

13. Advice on Optimal Orthosis Functionality

If you are using the **User** app, you can display a support code if problems occur with your orthosis. You can then send this code to a qualified specialist in orthopaedic technology so that the error can be corrected more quickly. You can find the support code in the app under the menu item "Information".

13.1 System Knee Joint

Problem	Cause	Action
The system joint switches unintentionally into a locked state.	The battery is empty.	Charge the battery.
The system joint switches unintentionally into permanently unlocked mode.	There is a problem with the electronics.	Press and hold the MODE button for 17 seconds. This will cause a short beep to sound. After 6–10 seconds a longer beep will sound, and after an additional 10 seconds an extra long beep will sound. The orthosis will then switch into Deep Sleep mode (total power interruption) and will remain in Lock mode. The orthosis can still be used in a locked state. Contact a qualified specialist in orthopaedic technology.
The system joint remains unlocked.	The rotary switch is unlocked.	Set the rotary switch to the symbol.

13.2 Remote Control

Problem	Cause	Further Action
The controller does not respond to pressed buttons on the remote control.	There is an active connection between the **User** app and the controller.	Check whether the controller is still connected to the **User** app. Close the app.
	You are moving while pressing the button.	Remain still while pressing a button.
	The controller is in Sleep mode.	Move the orthosis slightly.

13.3 Controller

Problem	Cause	Further Action
When the MODE button is pressed, the LEDs do not light up.	The battery is not charged.	Charge the battery. If the problem remains, contact a qualified specialist in orthopaedic technology.
No devices are found during connection of the controller and the **User** app.	The controller was not in connecting mode.	Within 30 seconds of pressing the MODE button, establish a connection between the **User** app and controller (see paragraph 4). Check whether the LEDs light up (see paragraph 5.1) or whether a short and a longer beep tone can be heard. If the problem remains, contact a qualified specialist in orthopaedic technology.

14. Disposal

If you no longer need the orthosis, please return it to a qualified specialist in orthopaedic technology. The product must not be disposed of with the residual waste (fig. 10). If you have a defective controller, please also return it to a qualified specialist in orthopaedic technology.

fig. 10

15. Technical Data

NEURO HiTRONIC	
period of use	unlimited, excluding wear parts
protection type	IP44
operating mode	continuous operation

15.1 Ambient Conditions

Operation	
ambient temperature	-10°C – +40°C
	+5°C – +40°C when charging the battery, no exposure to direct sunlight
relative air humidity	0% – 95%, non-condensing air humidity
air pressure	1060mbar – 700mbar

Transport	
ambient temperature	-25°C – +60°C
relative air humidity	without original packing: max. 95%, non-condensing air humidity with original packing: max. 95%
air pressure	1060mbar – 700mbar

Storage	
ambient temperature	+5°C – +40°C, no exposure to direct sunlight
relative air humidity	max. 95%, non-condensing air humidity
air pressure	1060mbar – 700mbar

Data Transmission	
remote technology	Bluetooth Low Energy (BLE4.2)
working range	min. 2m
operating frequency	2.4GHz
frequency range	2400MHz – 2483.5MHz
nominal channel bandwidth	2MHz, 40 channels
modulation	GFSK
data rate (OTA)	1Mbps
output power	3.7dBm/2.344mW (less than 20mW)
maximum output power (EIRP)	4dBm

Power Supply Unit with Charging Cable (not Part of the Medical Device)	
article number	ET0780-01
manufacturer's designation	FW8002.1MUSB/05
ambient temperature in operation	0°C – +45°C
ambient temperature in storage	-40°C – +70°C
relative air humidity	10% – 90%rH
input voltage	100V – 240V (AC)
input frequency	50Hz – 60Hz
power	6W
output voltage	5V
output current	1400mA
Charging Cable (not Part of the Medical Device)	
article number	ET0710-01
length	1m

Controller Battery	
type	lithium-polymer battery
capacity	5Wh
operating time at room temperature and full battery charge after 3 years of use	Auto mode: 26 000 strides/Free mode: 24 hours
behaviour of the system knee joint during the charging process	The system knee joint has no function.

User and Expert App	
supported operating systems	at least Android 6.0 or iOS 12
supported operating systems smartwatch	at least Wear OS 3.0 or watchOS 4.2

16. Signs and Symbols

CE labelling according to Regulation (EU) 2017/745 for medical devices

medical device

article number

Do not dispose of electronic devices with household waste. Dispose of the device and accessories at official delivery points for electronic devices.

manufacturer

batch code

serial number

protect from heat

keep dry

temperature limit values for storage/for transportation

air humidity limit values for storage/for transportation

air pressure limit values for storage/for transportation

follow the instructions for use (white on blue background)

single patient – multiple uses

IP44 protection from the ingress of solid foreign bodies (diameter ≥ 1.0mm) and from splashing water on all sides

UDI Unique Device Identifier – product identification number

Remote Control Type Plate

Controller Type Plate

17. CE Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of Regulation (EU) 2017/745. Therefore, the FIOR & GENTZ products bear the CE marking.

The product satisfies the requirements of the RoHS Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, for limiting the use of specific hazardous substances in electrical and electronic equipment.

18. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply. The warranty expires, for example, if the product is mounted several times. Please note that the product is not supposed to be combined with other components or materials than with those recommended in the configuration result of the FIOR & GENTZ Orthosis Configurator. The combination of the product with products from other manufacturers is not permitted.

The information in these instructions for use is valid at the date of printing. The contained product information serves as guidelines. Subject to technical modifications.

All copy rights, particularly the distribution, copy and translation of these instructions for use or any part of them, must be authorised by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH. Reprints, copies and any other electronic reproductions, even partial, are not permitted to be distributed without being authorised in writing by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH.

19. Electromagnetic Compatibility

Special precautions must be taken for all electronic medical devices as regards electromagnetic compatibility (EMC). This device complies with standard IEC 60601-1-2:2022-01.

- All electronic medical devices must be installed and put into operation in compliance with the EMC-relevant information contained in these instructions for use.
- Portable and mobile RF communication devices may interfere with the performance of electronic medical devices.

The device satisfies all valid and required standards for electromagnetic disturbances.

- It generally has no effect on systems and devices found in its vicinity.
- It is generally not affected by systems and devices found in its vicinity.
- It is not safe to operate the device in the vicinity of high-frequency surgical devices.
- It is recommended that the device not be used in the direct vicinity of other devices.

19.1 Electromagnetic Environment

Operation of the device is allowed in the following electromagnetic environments:

- professional health care facilities (e.g. hospital, etc.)
- home health care areas (e.g. use at home, use outdoors)

The patient must ensure that the device is exclusively operated in such environments.

19.2 Electromagnetic Emissions for all Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Emissions

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** must ensure that it is operated exclusively in such an environment.

Interference Measurements	Compliance	Usage Instructions for Electromagnetic Environment
RF emissions according to CISPR 11	group 1	The product **NEURO HiTRONIC** uses RF energy only for its internal function. Therefore, the RF emissions are very low and unlikely to cause any interference in nearby electronic devices.
RF emissions according to CISPR 11	class B	The product **NEURO HiTRONIC** is suitable for use outside of residential facilities. It is also suitable for facilities directly connected to a public low-voltage network that supplies residential buildings.
harmonics according to IEC 61000-3-2	class A	
voltage fluctuations/flicker according to IEC 61000-3-3	complies with requirements	

19.3 Electromagnetic Immunity for all Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level	Usage Instructions for Electromagnetic Environment
electrostatic discharge (ESD) according to IEC 61000-4-2	± 8kV discharge on contact ± 2kV, ± 4kV, ± 8kV, ± 15kV discharge through air	± 8kV discharge on contact ± 15kV discharge through air	Floors should be made of wood or concrete or be ceramic tiled. If the floor covering is made of synthetic material, the relative humidity must be at least 30%.
electrical fast transients/bursts according to IEC 61000-4-4	± 2kV for power supply lines 100kHz pulse repetition frequency	± 2kV for power supply lines	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
surges according to IEC 61000-4-5	± 0.5kV, ± 1kV line-to-line voltage ± 0.5kV, ± 1kV line-to-ground voltage	± 1kV line-to-line voltage ± 1kV line-to-ground voltage	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
voltage drops, short interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	0% of U_T for 0.5 cycles and phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 70% of U_T for 25/30 cycles and phase angles of 0° 0% of U_T for 250/300 cycles	0% of U_T for 0.5 cycles and phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 70% of U_T for 25/30 cycles and phase angles of 0° 0% of U_T for 250/300 cycles	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
magnetic field at mains frequency (50, 60Hz) according to IEC 61000-4-8	30A/m	30A/m	The magnetic fields at mains frequency should be equivalent to the typical levels of a commercial or hospital environment.
Note: U_T is the nominal voltage before applying the test levels.			

19.4 Electromagnetic Immunity for Non-Life-Supporting Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level	Usage Instructions for Electromagnetic Environment
conducted RF interference according to IEC 61000-4-6	$3V_{rms}$ 150kHz to 80MHz $6V_{rms}$ in ISM bands 150kHz to 80MHz	$3V_{rms}$ 150kHz to 80MHz $6V_{rms}$ in ISM bands 150kHz to 80MHz	Portable and mobile wireless devices should be used at a safety distance from the product **NEURO HiTRONIC** and its lines. The recommended safety distance was calculated using the equation applicable to the transmission frequency. Recommended safety distance: d = 1.2 √P d = 1.2 √P 80MHz to 800MHz d = 2.3 √P 800MHz to 2.7GHz P is the nominal output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). According to an on-site investigation[a], the field strength of stationary radio transmitters should be below the compliance level at all frequencies. Interference may occur in the vicinity of devices marked with the following symbol:
radiated RF interference according to IEC 61000-4-3	10V/m 80MHz to 2.7GHz 80% AM 1kHz	10V/m 80MHz to 2.7GHz	

Note 1: the higher frequency range applies between 80MHz and 800MHz.
Note 2: these guidelines may not be applicable in all cases. The propagation of electromagnetic factors is affected by absorption and reflection from buildings, objects and people.

[a] The field strength of stationary RF transmitters such as base stations of radio telephones and mobile land radio equipment, amateur radio stations, AM and FM radio and television stations cannot be precisely determined in advance. A site survey is recommended to establish the electromagnetic environment as a result of stationary RF transmitters. If the field strength determined at the site of the product **NEURO HiTRONIC** exceeds the compliance level specified above, the product **NEURO HiTRONIC** has to be monitored with regard to normal operation during use. If unusual performance characteristics are noted, additional measures may be necessary, such as changing the orientation or site of the product **NEURO HiTRONIC**.

19.5 Electromagnetic Immunity to Proximity Magnetic Fields

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity to Proximity Fields in the Frequency Range of 9kHz to 13.56MHz

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level
proximity magnetic fields according to IEC 61000-4-39	30kHz[a], CW, 8A/m 134.2kHz, pulse modulation[b] 2.1kHz 65A/m_{rms} 13.56MHz, pulse modulation[b] 50kHz 7.5A/m_{rms}	30kHz[a], CW, 8A/m 134.2kHz, pulse modulation[b] 2.1kHz 65A/m_{rms} 13.56MHz, pulse modulation[b] 50kHz 7.5A/m_{rms}

[a] Applicable only to medical devices and systems intended for use in a home healthcare environment.
[b] The carrier must be modulated with a square wave signal with 50% duty cycle.

19.6 Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product **NEURO HiTRONIC** for Non-Life-Supporting Devices and Systems

Usage Instructions and Manufacturer's Declaration – Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product NEURO HiTRONIC

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment where RF interference is monitored. The customer or user of the product **NEURO HiTRONIC** can help prevent electromagnetic interference by complying with the minimum distances between portable and mobile RF communication equipment (transmitters) and the product **NEURO HiTRONIC**, as specified below according to the maximum output of the communication equipment.

Nominal Output of the Transmitter [W]	Safety Distance [m] According to Transmission Frequency		
	150kHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters whose maximum nominal output is not specified in the table above, the recommended safety distance d in metres (m) can be determined using the equation in the respective column, where P stands for the maximum nominal output of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: the higher frequency range applies between 80MHz and 800MHz. Note 2: these guidelines may not be applicable in all cases. The propagation of electromagnetic factors is affected by absorption and reflection from buildings, objects and people.			

19.7 Test Specifications for the Immunity of Enclosures Against Wireless RF Telecommunication Equipment

Test Frequency [MHz]	Frequency Band[a] [MHz]	Radio Service[a]	Modulation[b]	Maximum Output [W]	Distance [m]	Immunity Test Level [V/m]
385	380 to 390	TETRA 400	pulse modulation[b] 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM[c] ± 5kHz deviation 1kHz sine	2	0.3	28
710	704 to 787	LTE band 13, 17	pulse modulation[b] 217Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	pulse modulation[b] 18Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	pulse modulation[b] 217Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	pulse modulation[b] 217Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	pulse modulation[b] 217Hz	0.2	0.3	9
5500						
5785						

Note: if necessary, the distance between the transmitting antenna and the ME device or ME system can be reduced to 1m to achieve the immunity test levels. The 1m test distance is permitted according to IEC 61000-4-3.

[a] For some radio services, only the frequencies for the radio link from the mobile communication device to the base station (uplink) have been included in the table.
[b] The carrier must be modulated with a square wave signal with 50% duty cycle.
[c] As an alternative to frequency modulation (FM), a pulse modulation of 50% at 18Hz can be used, as it does not correspond to the actual modulation, but is the worst case.

19.8 USA: FCC Regulatory Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and radiates radio frequency energy and, if not installed and used in accordance with the instructions for use, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.

19.9 Canada: ISED Regulatory Compliance Statement

This device complies with Industry Canada licence-exempt RSS standard(s).

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

RSS-102 Statement:

This device complies with Industry Canada radiation exposure limits set forth for an uncontrolled environment.

CAN ICES-003(B)

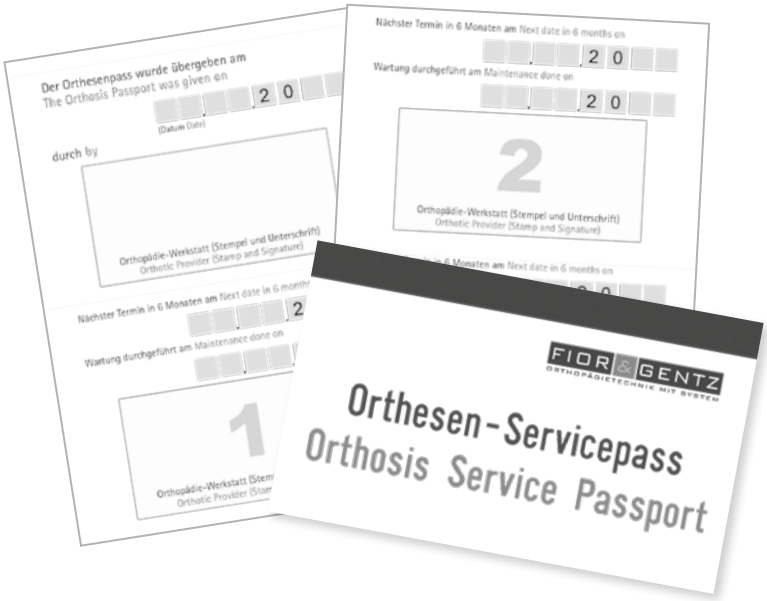
20. Handing Over the Orthosis

The qualified specialist in orthopaedic technology made sure that the instructions for use for patients as well as the orthosis service passport were also handed over with the orthosis to the patient, parents or care team. By means of these instructions for use, the functions and handling of the orthosis were explained to the patient in detail. The next maintenance appointment was entered in the orthosis service passport. The patient was asked to bring the orthosis service passport along to every maintenance appointment.

FIOR & GENTZ

ORTHOSIS SERVICE PASSPORT

Have you not yet received an orthosis service passport?
Ask the qualified specialist in orthopaedic technology!



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CE

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